

ANTIVIRAL COMPOSITION DERIVED FROM ALLIUM  
CEPA AND THERAPEUTIC USE THEREOF

IDS  
A1

Field of the Invention

The invention relates to a novel plant extract and therapeutic use thereof. More particularly, the present invention relates to the use of a novel plant extract for treating  
10 AIDS and other viral infections.

Background of the Invention

The use of plant derived compositions as therapeutic agents has been known for thousands of years. In particular, the Chinese are known for their herbal therapies. Recently, there has been a resurgence in the use of natural and plant-derived materials  
15 that supposedly possess therapeutic activity and promote general well being. For example, many persons now take St. John's Wort, purportedly to alleviate depression and promote general well being. Also, Ginkgo Biloba, purportedly to enhance memory, is widely used now. Further, SAME, a yeast-derived material which purportedly is useful for treatment of osteoarthritis and alleviation of depression, is in wide use.

20 In particular, the use of materials derived from a plant of the Allium family, especially *Allium sativum* ("garlic") has been reported in the literature. For example, several patents by Tatarintsev et al report the use of ajoene compound, derived from the garlic plant, for treating a variety of ailments including AIDS, inflammation, arthritis, transplant, infection, autoimmune diseases such as lupus, tuberculosis, tumors, and other  
25 relates diseases. (See U.S. Patents 5,856,363; 5,863,955; 5,948,821; and 5,932,621.)

Also, Hibi, U.S. Patent 5,612,077, describes an ajoene-containing extract from garlic for use in treating arteriosclerosis, tuberculosis, and bronchitis. Further, Tsuei, U. S. Patent 4,795,636; Seebeck, U.S. Patent No. 2,642,374; and Spinka et al, U.S. Patent No. 2,618,561, describe garlic extracts as medicinal agents.

5 Further, the isolation of compounds from plant materials, including *Allium* that inhibit apoptosis has been reported. See especially, U.S. Patents 5,567,425; 5,759,548; 4,986,985; 5,620,885; 5,624,672; 5,635,186; and 5,635,187, by Bathurst et al, all of which are incorporated by reference in their entirety herein.

10 The foregoing is only exemplary of plant-derived materials reported to possess medicinal properties. However, notwithstanding the large number of plant-derived materials reported to possess therapeutic properties, there still exists a need for novel plant extracts and therapeutic use thereof as such therapies may be safer and more cost effective than traditional medical treatments.

#### Objects of the Invention

15 It is an object of the invention to provide a novel plant extract derived from a plant species of the family *Alliaceae* (also known as *Lilliaceae* or *Amaryllidaceae*), preferably of the genus *Allium*, with the proviso that said *Allium* is not garlic (*Allium sativum*), having medicinal properties.

20 It is a more specific object of the invention to provide novel plant extracts derived from an *Allium* species selected from the group consisting of *Allium cepa*, *Allium*

*ampeloprasum* ("leek"), *Allium fistulosa* (Japanese bunching onion, scallion or Welsh onion), or *Allium schoenoprasum* ("chives") having medicinal properties.

It is an even more specific object of the invention to provide a novel plant extract derived from *Allium cepa*, preferably *Allium cepa* var. *Ancasti* or Southporth white glove (SWG) having medicinal properties.

It is a more specific object of the invention to provide a novel method of treating or preventing a retroviral infection such as HIV-1 or HIV-2 or AIDS by administering a plant extract derived from an *Allium* species other than *Allium sativum*, preferably *Allium cepa*, *Allium fistulosa*, *Allium ampeloprasum* or *Allium schoenoprasum*, and most preferably *Allium cepa*.

It is a more specific object of the invention to treat wasting syndrome, especially associated with AIDS, and/or to lengthen the latency period of HIV infection, and/or to delay the latent phase of AIDS, and/or to ameliorate or eliminate the clinical symptoms associated with AIDS such as intestinal problems, diarrhea, neurological impairment and paresthesia by administering a medicinal extract derived from an *Allium* species other than *Allium sativum*, preferably *Allium cepa*, *Allium fistulosa*, *Allium ampeloprasum* or *Allium schoenoprasum*, and more preferably *Allium cepa*.

It is another specific object of the invention to inhibit or treat microbial infection, e.g., fungal, yeast or *Candidiasis* infection in a subject in need of such inhibition or treatment, comprising administering a medicinal extract derived from an *Allium* species

other than *A. sativum*, preferably *Allium cepa*, *Allium fistulosa*, *Allium ampeloprasum* or *Allium schoenoprasum* and most preferably *Allium cepa*.

It is another specific object of the invention to modulate the immune system of a subject in need of such treatment, by administering a medicinal extract derived from an *Allium* species other than *Allium sativum*, preferably *Allium cepa*.

It is an object of the invention to provide a novel method of treating or preventing viral infection by administering a medicinal extract derived from an *Allium* species other than *Allium sativum*.

It is a more specific object of the invention to provide a novel method of treating or preventing viral infection by administering a medicinal extract derived from an *Allium* species selected from the group consisting of *Allium cepa*, *Allium ampeloprasum*, *Allium fistulosa*, and *Allium schoenoprasum*.

It is an even more specific object of the invention to provide a novel method of treating or preventing viral infection by administering a medicinal extract derived from *Allium cepa*, preferably the variety *Ancasti* or Southport white glove.

It is another object of the invention to immunostimulate the immune system of a subject in need of such treatment by administering a medicinal extract derived from an *Allium* species other than *sativum*, preferably *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum* or *Allium ampeloprasum* and more preferably *Allium cepa*.

It is another object of the invention to enhance T cell function and/or T cell proliferation, and/or T-cell differentiation, by administering a medicinal extract derived from an *Allium* species other than *Allium sativum*, preferably *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum* or *Allium ampeloprasum*, most preferably *Allium cepa*.

5 It is another specific object of the invention to identify and isolate the active constituent or constituents comprised in the *Allium* extract disclosed herein having antimicrobial, antifungal, antiviral, immunomodulatory, T cell function or proliferation inducing, and/or immunostimulatory activity.

10 It is another specific object of the invention to promote weight gain in a subject in need of such treatment by administering an effective amount of a medicinal extract derived from an *Allium* selected from *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum* or *Allium ampeloprasum*, most preferably *Allium cepa*.

15 It is another object of the invention to treat animal microbial infections, especially viral infections such as distemper or parvovirus or bacterial infections such as psittacosis, by administering a medicinal extract derived from *Allium cepa*.

It is another object of the invention to provide a method for producing a medicinal extract from *Allium* species selected from *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum* or *Allium ampeloprasum*.

It is another object of the invention to provide a novel medicinal extract derived from *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum*, or *Allium ampeloprasum*, preferably orally administrable.

5 It is another specific object of the invention to provide a novel regimen for treating AIDS that includes a dietary regimen, no administration of conventional AIDS medications such as protease inhibitors, anti-retrovirals, or other chemotherapeutics causing multiple side effects (other than antibiotics) and administration of a medicament derived from a plant of the genus *Allium*, preferably *Allium cepa*.

#### Detailed Description of the Invention

10 The present invention is based on the discovery that plants of the family *Alliaceae*, specifically those of the genus *Allium*, including *Allium cepa*, and related species such as *Allium fistulosa*, *Allium schoenoprasum*, and *Allium ampeloprasum*, can be used to obtain plant extracts having significant medicinal properties. In particular, it has been surprisingly discovered that extracts derived from *Allium* species, preferably *Allium cepa*,  
15 have wide ranging medicinal properties, including antiviral activity, antimicrobial activity (antifungal, antibacterial), immunomodulating activity, immunostimulating activity, T-cell function and/or T-cell proliferation and/or T-cell differentiation enhancing activity, and weight gain promoting activity.

20 This discovery is surprising in the fact that onions, while anecdotally reported to possess some medicinal properties, e.g., inhibition of thrombocyte aggregation and lipid

and blood pressure lowering activity, have never been suggested to possess the wide ranging medicinal activities discovered by the present inventors, especially regarding AIDS.

Therefore, the subject invention provides novel medicinal extracts and methods of use thereof, wherein such medicinal extracts are derived from a plant of the family *Alliaceae* (also known as *Liliaceae* or *Amaryllidaceae*), preferably *Allium* but excluding *Allium sativum*, and preferably *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum* or *Allium ampeloprasum*. Most preferably, the novel medicinal extracts of the present invention will be derived from onion (*Allium cepa* L.).

The onion, *Allium cepa* L. ( $2n = 16$  diploid), is a monocotyledon of the family *Alliaceae* which is by far the most economically important bulb vegetable. It is thought that the onion originated in Persia (Nonnecke, IL., "Vegetable Production", Van Nostrand Reinhold, NY (1989)) cultivated by the Egyptians, Greeks and Romans and brought to North America by the Spaniards. The onion has long been considered to possess medicinal value (Nonnecke (*Id.*)).

*Allium cepa* is divided into three main groups.

1. The common onion — bulbs are formed as single plants, and the inflorescence does not form bulbets (Nonnecke, (*Id.*)1989). The bulk of the onion cultivars belong to this group, which is the most important commercially (Nonnecke, (*Id.*)1989). It is propagated in the main from true seeds. Within this group exist extremes

of bulb shapes (present-day cultivars include the Sweet Spanish, Bermuda, and globe onions), dry scale color (white, yellow, and red predominating), pungency (ranging from mild and sweet to pungent), and other characteristics (Nonnecke, (*Id.*)1989). When harvested early they produce spring or bunching onions (Lorenz, Onion, In "The Software Toolworks Multimedia Encyclopedia", Version 1.5, Grolier, Inc. (1992)). The onion plant is potentially a biennial, producing large bulbs the first year and seed the next (Lorenz, (*Id.*)1992). Plants may be grown from seed, as transplants of seedlings, or as small bulbs (sets) produced from thickly planted seed; when replanted, these bulbs reach maturity rapidly (Lorenz, (*Id.*)1992). Mature onions are usually dried before marketing (Lorenz, (*Id.*)1992).

2. The aggregatum group --- characterized by many lateral bulbs or shoots, inflorescences lacking bulbets, sterile seed production, and propagation by vegetative means (Nonnecke, (*Id.*)1989). This group includes the potato onion or multiplier onion, ever-ready onions, and shallots (shallots are sometimes called scallions, a source of confusion because *A. fistulosum* is also called scallions) (Nonnecke, (*Id.*)1989).

3. The proliferous (proliferum) group --- in this group, ground bulbs are sometimes poorly developed, the inflorescence bears bulbets, true seed is usually lacking, and therefore reproduction is by vegetative inflorescence and bulbets (Nonnecke, (*Id.*)1989). These are not commercially cultivated; they are used almost exclusively for

home gardening (Nonnecke, (*Id.*)1989). The most common names for this group are tree  
onions, top-set onions, and Egyptian onions (Nonnecke, (*Id.*)1989).

5 The common onion (1. above), is a herbaceous biennial normally producing seed  
stems in the form of an umbel consisting of florets (Nonnecke, (*Id.*)1989). The swollen  
base of the stem forms a bulb made up of numerous fleshy leaves (Nonnecke, (*Id.*)1989).  
Short day length varieties are adapted for use in areas south of 30°N (Nonnecke,  
(*Id.*)1989). Medium day length varieties are adapted to mild areas from 30°N to about  
38°N, in areas where comparatively mild winters occur: south to central California,  
Georgia and mid-Atlantic states (Nonnecke, (*Id.*)1989). The long day onions are adapted  
10 for spring seeding or transplanting in sites north of 38°N (Nonnecke, (*Id.*)1989). The  
longer day length compensates for the shortness of the growing season by providing  
longer periods of photosynthetic activity (Nonnecke, (*Id.*)1989). It is absolutely critical  
to choose the appropriate cultivar for the appropriate environment; when short-day  
cultivars are grown in a long-day growing area or vice versa, the onion will not perform  
15 as expected (Nonnecke, (*Id.*)1989).

Onions for dehydration are white and have high soluble solids (Nonnecke,  
(*Id.*)1989). They are grown mostly in California where the long growing season permits  
the right balance of solids and pungency desired for the dehydrated product (Nonnecke,  
(*Id.*) 1989). The American market classifies onions according to maturation time  
20 (Nonnecke, (*Id.*)1989). The Bermuda Granex, a grano type that is mild and flat top

shaped, is an early-maturing onion with little or no storage life (Nonnecke, (*Id.*)1989). The late crop onions, mostly globe shaped with yellow, white or red scales are mild or pungent depending on cultivar and environment, and usually store well over long periods (Nonnecke, (*Id.*)1989). The bulk of the seed is produced in an environment conducive to good seed set, such as California (Nonnecke, (*Id.*)1989).

In general, the medicament of the present invention which is derived from *Allium cepa*, *Allium fistulosa*, *Allium schoenoprasum* or *Allium ampeloprasum*, and preferably *Allium cepa*, more preferably type *Ancasti* and Southporth white glove, is produced by dehydration of an *Allium* plant material other than *Allium Sativum* by one or more heating steps, typically effected at about 80°C/110°C or higher, i.e., after an initial washing procedure, removal of non-viable materials and removal of other impurities such as stones, wires, etc., and processing of the dehydrated material into fine particles or granules, i.e., roughly having the consistency of talcum powder or confectionary sugar, such that the average particle size ranges from about 1 to 1,400 microns and, more preferably, ranges from about <250 to about 850 microns. This granulation or particulation procedure can be effected or known industrial devices for effecting granulation, or in particular by use of high speed cutters such as those available from Moulinex or other suppliers. Such granulation will preferably be effected at low humidity, e.g.,  $\leq$  5%-7% humidity, in order to prevent aggregation or clumping of particles or granules during processing. It is hypothesized by the present inventors that the particulate

size of the subject medicament may enhance its medicament properties, perhaps because of increased surface area. Alternatively, it is speculated that particles of such size may facilitate absorption or uptake of the active constituent by specific cells, e.g., immune cells, and thereby potentiate its effect on the immune system.

5 Preferably, the utilized procedure for particulating the processed dehydrated *Allium*, preferably *Allium cepa*, material will result in most (greater than 95%) of the particles or granules in the resultant composition having an average size ranging from 1 to 1,400 microns, more preferably most of the particles will have an average particle size in the range of  $\leq 10$  microns to about 850 microns, and most preferably most of the  
10 particles will have an average size within the range of 36 to 500 microns.

A preferred procedure for producing an *Allium* medicinal extract according to the invention comprises the following steps. This process is exemplary of the processes that can be used to produce the novel medicinal extract of the invention. Indeed, it is anticipated that the ordinary routineer will be able to modify this procedure without  
15 adverse effects, e.g., to reduce costs and enhance efficacy.

In the exemplary process, an *Allium* plant material, preferably *Allium cepa*, *Allium fistulosa*, *Allium ampeloprasum* or *Allium schoenoprasum*, preferably *Allium cepa*, including at least the bulb portion of the plant, is obtained. In a preferred embodiment, the selected *Allium cepa* material will comprise *Allium cepa* variety *ancasti* or Southporth  
20 white glove. However, this is not essential to the invention, and other *Allium cepa*

varieties may alternatively be utilized. Preferably, the selected *Allium cepa* or above-identified *Allium* species will be grown in the absence of herbicides, insecticides and other agrochemicals such as organic fertilizers. However, this also is not essential to the invention.

5           This *Allium* plant material, which includes especially the bulb portion of the plant, may be stored prior to medicament preparation, preferably under cold conditions, typically about 10°C at 70% humidity, or about 5 - 15°C at 60-80% humidity. For example, the *Allium* plant material may be stored in wooden boxes (bines) for prolonged period, e.g., at least 30 days, and up to about 4 months. If stored for longer periods, the  
10           active constituents may lose their activity, e.g., because of natural decomposition of the onion over time.

          Thereafter, the *Allium* plant material containing the bulb portion, optionally after it has been stored under appropriate conditions undergoes a quality evaluation. This material may also be classified based on size of plant materials.

15           Thereafter, the plant material is subjected to one or more washing procedures. Preferably, this washing will be effected under abrasive conditions on a conveyor belt which comprises use of an acidic aqueous washing solution, preferably a chlorinated aqueous solution. In a preferred embodiment, the washing solution will contain about 100 to 120 parts per million of chlorine. Preferably, no other chemical additives will be  
20           utilized during the washing procedure to eliminate fungus or bacteria. As noted, the

washing is effected under abrasive conditions, i.e., the bulbs are also treated by abrasion, e.g., by a brushing procedure, at this time to remove the outer layers. Thereafter, one or more additional washing steps are then preferably effected, again using a chlorine-containing aqueous washing solution, preferably a cold chlorine-containing aqueous solution.

More specifically, the subject medicament is produced using an industrial process that complies with the F.D.A. regulations of the U.S.A. under the quality ISO 9000 norms. Preferably, the bulb recollection is industrial, not manual. After collection, the bulbs are preferably stored in wooden boxes of 1m x 1m x 1m called bines. To maintain stability, such bulbs are stored in chambers at an average of 10°C at 70% humidity (5-15°C and 60-80% humidity.) The normal storage does range between 30 and 120 days. This is followed by a quality evaluation (defects, solid material content, etc.). The optionally sorted bulbs are then sent to the elaboration plant.

The vegetal material is loaded in a large recipient or feeder to transport the material by a conveyor belt to start the first step in the process. In one embodiment the conveyor belt is made of a sequence of cylinders with brushes upon which the vegetal material rolls. Thereafter, "washing by abrasion" is effected with cold chlorinated water (e.g., about 7 to 15°C). The chlorine concentration preferably ranges from 100 to 120 parts per million. No additive is used to eliminate fungus and bacteria. The bulbs are

also brushed to eliminate the outer layers. This process of washing by abrasion is repeated a second time under identical conditions.

5 A belt is then used to transport the bulbs to the place where the material is sorted, e.g., manually, by discarding the non-viable one (e.g., green non-comestible or rotten material.) Thereafter, the material goes through a process of decantation eliminating foreign bodies such as stones, wires, etc. The bulbs are then cut into thin slices (e.g. 2-7 mm), preferably about 2-4 mm., e.g., by use of a cutting machine, to help the process of selection and dehydration. This is followed by the process of dehydration. For example, in one embodiment, the material is transported using another belt, and the transported material is preferably then heated, e.g. in an oven of dry continuous heat, and preferably 10 first at 80-100°C for 45 minutes, followed by 90-110°C for another 45 minutes, and finally dehydration is completed at 80-100°C for 30 minutes. This final material (called virgin) contain 5-7% humidity. However, it is anticipated that the heating process may be varied without adverse effects.

15 The virgin is kept in sealed bags at 20 to 25°C, preferably under dark conditions, until it will be needed. When needed for use, the "virgin" material is then processed with another machine that strips the outer layers and leaves the pulp by pneumatic separation. In this way, the slices obtained are of pulp material. This pulp is then chopped into flakes, which preferably are kept sealed at 18-25°C, away from sunlight.

After drying, the plant material, which consists of the pulp (and optionally outer layers) is then loaded into an industrial processing device, e.g., high speed cutters. Other option is the use of devices such as "Moulinex", or from other suppliers, that processes this material into fine particles or granules.

5            Preferably this granulation is effected at very low humidity, i.e., maximum of about 5.5% humidity to avoid clumping, in order to provide granulates having an average particle size ranging from about 1 to 1,400 microns, more preferably from about  $\leq 36$  microns to 850 microns. The dried particles will typically comprise at most 5.5% water, and preferably less. In an exemplary composition produced according to the invention  
10           from *Allium cepa*, about 42.9% of particles were smaller than 250 microns, 56.9% were less than 355 microns, 74.7% were less than 500 microns, and 21.7% were between 500-850 microns, with 22.1% ranging from 106-250 microns, 6.8% ranging from 75-106 microns, 10.8% ranging in size from 36-75 microns, and 3.2% being  $< 36$  microns. Thus, the significant majority of particles are less than 500 microns, with most ranging from  
15            $< 36$  to 850 microns.

The dried particulate material may be immediately used as a medicament or it may be stored for a prolonged time prior to usage. This material preferably will be stored under cold (typically about 18 to 25°C), dark conditions, for up to a year or even longer. This will prevent degradation of active constituents, e.g., by oxidation or sunlight.

It is believed that the subject treatment process which essentially comprises acidic washing steps, heated dehydration, and granulation into very fine particles having the consistency of a fine powder, e.g., on the order of talcum powder, results in an extract having a substantially unchanged chemical composition from the original *Allium* material, except for the removal of water, scent, and some other volatile acids.

However, the present inventors do not rule out the possibility that the washing, dehydration process and the heating steps used in the subject matter may be facilitating one or more reactions that result in the formation of one or more medicament compounds that are not endogenously present in *Allium* or which were present in lower concentrations, may provide for the release of larger amounts of active constituents. With respect thereto, the subject inventors are uncertain as to what are the exact active constituent or constituents that are contained in the subject medicament composition.

However, it has been reported that *Allium cepa* comprises the compounds listed below.

15 1-(F)- $\beta$ -FRUCTOSYL-SUCROSE  
1-(METILSULFINYL)-PROPYL-METHYL-DISULFIDE  
1-METHYLDITHIO-PROPANE  
1-METHYLTRITHIO-PROPANE  
1-O-CAFFELOYL- $\beta$ -D-GLUCOSE  
20 1-O-FERULOYL- $\beta$ -D-GLUCOSE  
1-O-P-COUMAROYL- $\beta$ -D-GLUCOSE  
1-PROPYLTRITHIOPROPANE  
2,3-DIMETHYL-(D,L)-BUTANE-CIS-1-CIS-DITHIAL-S,S'-DIOXIDE  
2,3-DIMETHYL-5,6-DITHIA-BICYCLO-(2,2,1)-HEXANE-5-OXIDE

2,3-DIMETHYLTHIOPHENE  
2,4-DIMETHYLTHIOPHENE  
2,5-DIMETHYLTHIOPHENE  
24-METHYLENE-CYCLOARTENOL  
5 28-ISOFUCOSTEROL  
2-METHYL-BUT-2-EN-1-AL  
2-METHYL-BUTANAL  
2-METHYL-BUTYR-2-ALDEHYDE  
2-METHYL-PENT-2-EN-1-AL  
10 2-METHYL-PENTANAL  
3,4-DIMETHYL-2,5-DIOXO-2,5-DIHYDROTHIOPHENE  
3,4-DIMETHYLTHIOPHENE  
31-NORCYCLOARTENOL  
31-NORLANOSTENOL  
15 4- $\alpha$ -METHYL-ZIMOSTENOL  
5-DEHYDRO-AVENASTEROL  
5-HEXYL-CYCLOPENTA-1,3-DIONE  
5-METHYL-2-n-HEXYL-2,3-DIHYDROFURAN-3-ONE  
5-OCTYL-CYCLOPENTA-1,3-DIONE  
20 6(G)- $\beta$ -FRUCTOSYL-SUCROSE  
9,10,13-TRIHIDROXY-OCTADEC-11-ENOIC-ACID  
9,12,13-TRIHIDROXY-OCTADEC-10-ENOIC-ACID  
ABSCISSIC-ACID  
ACETAL  
25 ACETIC-ACID  
ALANINE  
ALLICIN  
ALLIIN  
ALLIOFUROSIDE-A  
30 ALLIOSPIROSIDE-A  
ALLIOSPIROSIDE-B  
ALLIOSPIROSIDE-C  
ALLIOSPIROSIDE-D

ALLYL PROPYL SULFIDE  
ALLYL PROPYL TRISULFIDE  
ALLYL-METHYL-DISULFIDE  
ALLYL-METHYL-SULFIDE  
5 ALLYL-METHYL-TRISULFIDE  
ALLYL-PROPENYL-DISULFIDE  
ALLYL-PROPYL-DISULFIDE  
ALLYLTHIOL  
ALUMINUM  
10 AMMONIA  
ARABINOSE  
ARACHIDIC-ACID  
ARGININE  
ARSENIC  
15 ASCORBIC-ACID  
ASH  
ASPARAGINE  
ASPARTIC-ACID  
BARIUM  
20 BENZYL ISOTHIOCIANATE  
BORON  
BRASSICASTEROL  
BROMINE  
CADMIUM  
25 CAFFEIC-ACID  
CALCIUM  
CALCIUM-OXALATE  
CAMPHESTEROL  
CARBOHYDRATES  
30 CATECHOL  
CEPAENES  
CEPOSIDE-D  
CHOLEST-7-EN-3- $\beta$ -OL

CHOLESTEROL  
CHOLINE  
CHROMIUM  
CIS-1-(PROPENYL-DITHIO)-PROPANE  
5 CIS-2,3-DIMETHYL-5,6-DITHIO-CYCLO(2,2,1)HEPTANE-5<sup>1</sup>OXIDE  
CIS-3,5-DIETHYL-1,2,4-TRITHIOLANE  
CIS-PROPANETHIOL-S-OXIDE  
CIS-PROPENYL-PROPYL-DISULFIDE  
CIS-PROPENYL-PROPYL-TRISULFIDE  
10 CITOSINE  
CITRIC-ACID  
CITRULINE  
COBALT  
COPPER  
15 CYANIDIN-3-O-LAMINARIBIOSIDE  
CYANIDIN-3-O- $\beta$ -D-DIGLYCOSIDE  
CYANIDIN-BIOSIDE  
CYANIDIN-DIGLYCOSIDE  
CYANIDIN-MONOGLYCOSIDE  
20 CYCLOALLIN  
CYCLOARTENOL  
CYCLOEUCALENOL  
CYSTEINE  
CYSTINE  
25 DIALLYL-DISULFIDE  
DIALLYL-SULFIDE  
DIALLYL-TRISULFIDE  
DIHYDROALLIN  
DIISOPROPYL-TRISULFIDE  
30 DIMETHYL-DISULFIDE  
DIMETHYL-FURANE  
DIMETHYL-SULFIDE  
DIMETHYL-TETRASULFIDE

DIMETHYL-TRISULFIDE  
DIMETHYL-TRISULFIDE  
DIPHENYLAMINE  
DIPROPENYL-DISULFIDE  
5 DIPROPENYL-SULFIDE  
DIPROPYL-DISULFIDE  
DIPROPYL-TRISULFIDE  
D-MANNITOL  
EICOSEN-1-OL  
10 EO  
ETHANOL  
ETHANOLAMINE  
FATS  
FERULIC-ACID  
15 FIBER  
FLUORINE  
FRUCTOSAN  
FRUCTOSE  
FUMARIC-ACID  
20 GIBERELLIN-A-4  
GLUCINE  
GLUCOFRUCTAN  
GLUCOSE  
GLUTAMINE  
25 GLUTAN  
GLYCINE  
GLYCOLIC-ACID  
GRAMISTEROL  
HEXADECEN-1-OL  
30 HISTIDINE  
HYDROGEN SULFUR  
IRON  
ISOLEUCINE

ISOPROPYL-PROPYL-DISULFIDE  
ISOPROPYL-PROPYL-TRISULFIDE  
KAEMPFEROL  
KAEMPFEROL-3,4'-DI-O- $\beta$ -D-GLUCOSIDE  
5 KAEMPFEROL-4',7-DI-O- $\beta$ -D-GLUCOSIDE  
KAEMPFEROL-4'-O- $\beta$ -D-GLUCOSIDE  
LEAD  
LEUCINE  
LINOLEIC-ACID  
10 LITHIUM  
LOPHENOL  
LYSINE  
MAGNESIUM  
MALIC-ACID  
15 MANGANESE  
MERCURY  
METHANOL  
METHANOTHIOL  
METHIONINE  
20 METHIONINE-METHYLSULFONUM  
METHIONINE--SULFONE  
METHYL-ALLIIN  
METHYL-CIS-PROPENYL-DISULFIDE  
METHYL-DITHIOMETHANE  
25 METHYL-METHANOTHIOSULFONUM  
METHYL-PROPENYL-SULFIDE  
METHYL-PROPENYL-TRISULFIDE  
METHYL-PROPYL-DISULFIDE  
METHYL-PROPYL-TRISULFIDE  
30 METHYL-TRANS-PROPENYL-DISULFIDE  
MEVALONIC-ACID  
MOLYBDENUM  
MUFA

MYRISTIC-ACID  
MYROSINASE  
NIACIN  
NICKEL  
5 NITROGEN  
NONADECANOIC-ACID  
N-PROPYL-MERCAPTAN  
OLEANOLIC-ACID  
OLEIC-ACID  
10 OXALIC-ACID  
PAEONIDIN-GLYCOSIDE  
PALMITIC-ACID  
PANTOTHENIC-ACID  
P-COUMARIC-ACID  
15 PECTIN  
PELARGONIDIN-MONOGLYCOSIDE  
PENTOSAN  
PEROXIDASE  
PHENILALANINE  
20 PBLOROGLUCINOL  
PHLOROGLUCYOL-CARBOXYLIC-ACID  
PHOSPHORUS  
P-HYDROXYBENZOIC-ACID  
PHYROCATECOL  
25 PHYTOHORMONE  
PHYTOSTEROLS  
PIPECOLIC-ACID  
POTASSIUM  
PROLINE  
30 PROPAN-1-OL  
PROPANAL  
PROPANALDEHYDE  
PROPANE-1-THIOL

PROP-CIS-ENYL-PROPYL-DISULFIDE  
PROP-CIS-ENYL-PROPYL-TRISULFIDE  
PROPENE  
PROPENYL-PROPYL-SULFIDE  
5 PROP-TRANS-ENYL-PROPYL-DISULFIDE  
PROP-TRANS-ENYL-PROPYL-TRISULFIDE  
PROPYL-METHANOTHIOSULFONATE  
PROPYL-PROPANOTHIOSULFONATE  
PROSTAGLANDIN-A-1  
10 PROTEIN  
PROTocatechuic-ACID  
PUFA  
PYRUVIC-ACID  
QUERCETIN  
15 QUERCETIN-3,4'-DI-0- $\beta$ -D-GLUCOSIDE  
QUERCETIN-3-0- $\beta$ -D-GLUCOSIDE  
QUERCETIN-4',7-DI-0-P-D-GLUCOSIDE  
QUERCETIN-4-0- $\beta$ -D-GLUCOSIDE  
QUINIC-ACID  
20 RAFFINOSE  
RHAMNOSE  
RIBOFLAVIN  
RIBOSE  
RUBIDIUM  
25 RUTIN  
S-(2-CARBOXY-PROPYL)-GLUTATHIONE  
S-( $\beta$ -CARBOXYBETA-METHYL-ETHER-CISTEINE  
S-ALLIL-CYSTEINE  
SAPONIN  
30 SELENIUM  
SELENO-CYSTEINE  
SELENO-METHIONINE  
SELENO-METHYLSELENOCYSTEINE

SELENO-METHYL-SELENOMETHIONINE  
SELENOSIDE  
SERINE  
SFA  
5 SILICON  
SILVER  
SINAPIC-ACID  
S-METHYL-CYSTEINE  
S-METHYL-CYSTEINE-SULFOXIDE  
10 SODIUM  
SPIRAEOSIDE  
S-PROP-1-ENYL-CYSTEINE-S-OXIDE  
S-PROPYL-1-ENYL CYSTEINESULFOXIDE  
S-PROPYL-CYSTEINE-SULFOXIDE  
15 STEARIC-ACID  
STIGMAST-7-EN-3- $\beta$ -OL  
STIGMASTEROL  
STRONTIUM  
SUCCINIC-ACID  
20 SUCROSE  
SULFUR  
TARTARIC-ACID  
THIAMIN  
THIOPROPANAL-S-OXIDE  
25 THIOPROPIONAL-S-OXIDE  
TITANIUM  
TRANS-1-(PROPENYL-DITHIO)-PROPANE  
TRANS-2,3-DIMETHYL-5,6-DITHIA-CYCLO-(2,2,1)-HEPTANE-5-OXIDE  
TRANS-3,5-DIETHYL-1,2,4-TRITHIOLANE  
30 TRANS-PROPENYL-PROPYL-DISULFIDE  
TRANS-PROPENYL-PROPYL-TRISULFIDE  
TRANS-S-(1-PROPENYL)-CYSTEINE-SULFOXIDE  
TREONINE

TREDECAN-2-ONA  
TRIGONELLINE  
TRYPTOPHAN  
TSEPOSIDES  
5 TULIPOSIDE-A  
TULIPOSIDE-B  
TYROSINE  
VALINE  
VANILLIC-ACID  
10 VIT-B-6  
WATER  
XYLITOL  
XYLOSE  
ZINC  
15 ZIRCONIUM  
 $\alpha$ -AMYRIN  
 $\alpha$ -SITOSTEROL  
 $\alpha$ -TOCOPHEROL  
 $\beta$ -ALANINE  
20  $\beta$ -CAROTENE  
 $\beta$ -SITOSTEROL  
 $\beta$ -TOCOPHEROL  
 $\gamma$ -ABULINE  
 $\gamma$ -AMINOBUTIRIC-ACID  
25  $\gamma$ -GLUTAMYL-LEUCINE  
 $\gamma$ -GLUTAMYL-METHIONINE  
 $\gamma$ -GLUTAMYL-PHENYLALANINE  
 $\gamma$ -GLUTAMYL-PHENYLALANINE-ETHYL-ESTER  
 $\gamma$ -GLUTAMYL-S-METHYL-CYSTEINE  
30  $\gamma$ -L-GLUTAMYL-ARGININE  
 $\gamma$ -L-GLUTAMYL-CYSTEINE  
 $\gamma$ -L-GLUTAMYL-ISOLEUCINE  
 $\gamma$ -L-GLUTAMYL-S-(1-PROPENYL)L-CYSTEINE-SULFOXIDE

γ-L-GLUTAMYL-S-(2-CARBOXY-N-PROPYL)L-CISTEINE  
γ-L-GLUTAMYL-S-(2-CARBOXY-β-METHYL-ETHYL)-CYSTEINYL-GLY  
γ-L-GLUTAMYL-S-(2-CARBOXY-β-METHYL-ETHYL)-CYSTEINYL-GLY  
γ-L-GLUTAMYL-VALINE  
5 CYANIDIN-3-MALONYLGLUCOSIDE  
CYANIDIN-3-MANOLYLAMINARIBIOSIDE  
PEONIDIN-3-GLUCOSIDE  
PEONIDIN-3-MALONYLGLUCOSIDE  
PHOSPHATASE  
10 PROPILENSULFIDE  
QUERCETIN-3,4'-O-β-DIGLUCOPYRANOSIDE  
QUERCETIN-3,7,4'-O-β-GLUCOPYRANOSIDE  
QUERCETIN-4'-O-β-GLUCOPYRANOSIDE  
TAXIFOLIN-4'-O-β-GLUCOPYRANOSIDE  
15 β-FRUCTOFURANOSIDASE  
γ-GLUTAMYLTRANSPEPTIDASE

Of the above materials, those that are especially hypothesized to be responsible for the medicinal and immune regulating activity of the subject *Allium* extract are set forth below.

20 1-O-CAFFELOYL-β-D-GLUCOSE  
1-O-P-COUMAROYL-β-D-GLUCOSE  
ALLICIN  
ALLIIN  
ALLIOFURÓSIDE-A  
25 ALLIOSPIRÓSIDE-A  
ALLIOSPIRÓSIDE-B  
ALLIOSPIRÓSIDE-C  
ALLIOSPIRÓSIDE-D  
ALLYL PROPYL SULFIDE  
30 ALLYL PROPYL TRISULFIDE  
ALLYL-METHYL-DISULFIDE

ALLYL-METHYL-SULFIDE  
ALLYL-METHYL-TRISULFIDE  
ALLYL-PROPENYL-DISULFIDE  
ALLYL-PROPYL-DISULFIDE  
5 CAFFÉIC-ACID  
CAMPHESTEROL  
CATECHOL  
CHOLINE  
CIS-PROPENYL-PROPYL-DISULFIDE  
10 CIS-PROPENYL-PROPYL-TRISULFIDE  
CYANIDIN-3-O-LAMINARIBIÓSIDE  
CYANEDIN-3-O-b-D-DIGLYCÓSIDE  
CYANIDIN-BIÓSIDE  
CYANIDIN-DIGLYCÓSIDE  
15 CYANIDIN-MONOGLYCÓSIDE  
CYCLOALLIN  
DIALLYL-DISULFIDE  
DIALLYL-SULFIDE  
DIALLYL-TRISULFIDE  
20 DIHYDROALLIN  
DIISOPROPYL-TRISULFIDE  
DIMETHYL-DISULFIDE  
DIMETHYL-SULFIDE  
DIMETHYL-TETRASULFIDE  
25 DIMETHYL-TRISULFIDE  
DIPROPENYL-DISULFIDE  
DIPROPENYL-SULFIDE  
DIEPROPYL-DISULFIDE  
DIPROPYL-TRISULFIDE  
30 HYDRÓGEN SULFUR  
ISOPROPYL-PROPYL-DISULFIDE  
ISOPROPYL-PROPYL-TRISULFIDE  
KAEMPFEROL-3,4'-DI-O-b-D-GLUCOSIDE

KAEMPFEROL-4',7-DI-O-b-D-GLUCOSIDE  
KAEMPFEROL-4'-O-b-D-GLUCOSIDE  
LYSINE  
METHIONINE-METHYLSULFONUM  
5 METHIONINE-SULFONE  
METHYL-ALLIIN  
METHYL-CIS-PROPENYL-DISULFIDE  
METHYL-METHANOTHIOSULFONUM  
METHYL-PROPENYL-SULFIDE  
10 METHYL-PROPENYL-TRISULFIDE  
METHYL-PROPYL-DISULFIDE  
METHYL-PROPYL-TRISULFIDE  
METHYL-TRANS-PROPENYL-DISULFIDE  
MYRISTIC-ACID  
15 MYROSINASE  
OLEANOLIC-ACID  
PAEONIDIN-GLYCOSIDE  
PALMITIC-ACID  
P-COUMARIC-ACID  
20 PELARGONIDIN-MONOGLYCOSIDE  
PROP-CIS-ENYL-PROPYL-DISULFIDE  
PROP-CIS-ENYL-PROPYL-TRISULFIDE  
PROPENYL-PROPYL-SULFIDE  
PROP-TRANS-ENYL-PROPYL-DISULFIDE  
25 PROP-TRANS-ENYL-PROPYL-TRISULFIDE  
PROPYL-METHANOTHIOSULFONATE  
PROPYL-PROPANOTHIOSULFONATE  
PROSTAGLANDIN-A-1  
QUERCETIN  
30 QUERCETIN-3,4'-DI-O-b-D-GLUCOSIDE  
QUERCETIN-3-O-b-D-GLUCOSIDE  
QUERCETIN-4',7-DI-O-b-D-GLUCOSIDE  
QUERCETIN-4-O-b-D-GLUCOSIDE

RUTIN  
S-ALLIL-CYSTEINE  
SAPONIN  
SELENIUM  
5 SELENO-CYSTEINE  
SELENO-METHIONINE  
SELENO-METHYLSELENOCYSTEINE  
SELENO-METHYL-SELENOMETHIONINE  
SELENÓSEDE  
10 S-METHYL-CYSTEINE-SULFÓXIDE  
S-PROPYL ENYL-1-ENYL CYSTEINESULFÓXIDE  
S-PROPYL-CYSTEINE-SULFÓXIDE  
SULFUR  
TRANS-PROPENYL-PROPYL-DISULFIDE  
15 TRANS-PROPENYL-PROPYL-TRISULFIDE  
TRANS-S-(1-PROPENYL)-CYSTEINE-SULFÓXIDE  
a-AMYRIN  
a-SITOSTEROL  
b-SITOSTEROL  
20 g-GLUTAMYL-LEUCINE  
g-GLUTAMYL-METHIONINE  
g-GLUTAMYL-PHENYLALANINE  
g-GLUTAMYL-PHENYLALANINE-ETHYL-ESTER  
g-GLUTAMYL-S-METHYL-CYSTEINE  
25 g-L-GLUTAMYL-ARGININE  
g-L-GLUTAMYL-CYSTEINE  
g-L-GLUTAMYL-ISOLEUCINE  
g-L-GLUTAMYL-S-(1-PROPENYL)L-CYSTEINE-SULFÓXIDE  
g-L-GLUTAMYL-S(2-CARBOXY-N-PROPYL)l-CISTEINE  
30 g-l, GLUTAMYL-S-(2-CARBOXY-b-METHYL-ETHYL)-CYSTEINYL-GLY  
g-L-GLUTAMYL-VALINE  
CYANIDIN-3-MALONYLGLUCÓSIDE  
CYANIDIN-3-MANOLYLAMINARIBIOSIDE

QUERCETIN-3,4'-O-b-DIGLUCOPYRANOSIDE  
QUERCETIN-3,7,4'-O-b-GLUCOPYRANOSIDE  
QUERCETIN-4'-O-b-GLUCOPYRANOSIDE

Of these compounds, the following are believed to be the most likely candidates  
5 to be separately or jointly responsible for the medicinal properties of the subject *Allium*  
extracts.

1-O-CAFFELOYL-b-D-GLUCOSE  
ALLICIN  
ALLIIN  
10 ALLYL PROPYL SULFIDE  
ALLYL PROPYL TRISULFIDE  
ALLYL-METHYL-DISULFIDE  
ALLYL-METHYL-SULFIDE  
ALLYL-METRYL-TRISULFIDE  
15 ALLYL-PROPENYL-DISULFIDE  
ALLYL-PROPYL-DISULFIDE  
CAFFÉIC-ACID  
CATECHOL  
CHOLINE  
20 DIHYDROALLIN  
KAEMPFEROL-3,4'-DI-O-b-D-GLUCOSIDE  
KAEMPFEROL-4',7-DI-O-b-D-GLUCOSIDE  
KAEMPFEROL-4'-O-b-D-GLUCOSIDE  
LYSINE  
25 METHYL-METHANOTHIOSULFONUM  
OLEANÓLIC-ACID  
PALMÍTIC-ACID  
P-COUMÁRIC-ACID  
PROPYL-METHANOTHIOSULFONATE  
30 PROPYL-PROPANOTHIOSULFONATE  
QUERCETIN

QUERCETIN-3,4'-DI-O-b-D-GLUCÓSIDE  
QUERCETIN-3-O-b-D-GLUCÓSIDE  
QUERCETIN-4',7-DI-O-b-D-GLUCÓSIDE  
QUERCETIN-4-O-b-D-GLUCOSIDE  
5 RUTIN  
SAPONIN  
SELENTUM  
a-AMYRIN  
a-SITOSTEROL  
10 b-SITOSTEROL  
CYANIDIN-3-MALONYLGLUCÓSIDE  
CYANIDIN-3-MANOLYLAMINARIBIOSIDE  
QUERCETIN-3,4'-O-b-DIGLUCOPYRANOSIDE  
QUERCETIN-3,7,4'-O-b-GLUCOPYRANOSIDE  
15 QUERCETIN-4'-O-b-GLUCOPYRANOSIDE

However, Applicants do not want to be bound by such hypotheses. In fact, it may be that the medicinal properties of the subject *Allium* extracts may involve different constituents, or may require a particular distribution of constituents that are selectively obtained by the afore-described processing procedure. Moreover, as discussed  
20 previously, the particulate size or other morphological properties of the material may also be significant to medicament activity.

The particles obtained by the described procedure may be administered by systemic or non-systemic means. Typically, the particles (in the form of a powder) will be placed in capsules that either dissolve in the stomach or intestine, or both, or will be  
25 used to make tablets, suppositories, sachets, or will liquid administrable forms, e.g., elixirs, syrups, or suspensions. Alternatively, these powders can be used to produce an

injectable composition, e.g., by addition to a pharmaceutically acceptable excipient such as buffered saline. Of these modes of administration, oral administration is preferred. For example, in a preferred embodiment, capsules containing the powder according to the invention may be ingested with an ingestible fluid, e.g., juice, water, or milk. Still  
5 alternatively, the powders will be added to a food, e.g. solid or liquid that camouflages the taste of the particles, especially if the user does not like the taste of onion.

Methods for producing orally administrable materials having desired properties, e.g., sustained or rapid release, enteric-coated forms, are well known and are described in *Remington's Pharmaceutical Sciences*, Mack Publishers (incorporated by reference  
10 herein.)

In producing capsules, the subject *Allium* powder may be combined with other materials, if desired, e.g, sugars such as lactose, sucrose, mannitol, starches, cellulose derivatives, magnesium stearate or stearic acid. Also, materials that enhance aesthetic properties of the material may be added, e.g., colorants and flavoring materials. Additives  
15 which can be utilized in capsule formulations are well known to those skilled in the art.

If the subject powders are utilized to make tablets, conventional tableting procedures can be used which typically comprise processing the materials by compression to produce a tablet. Materials which facilitate tablet formation can be utilized, e.g., binders and bulking agents or other additives, including by way of example gums, waxes;  
20 insoluble polymers, polyvinyl alcohol, polyethylene glycol, sucrose, lactose, acacin,

tragacanth, and polyvinyl pyrrolidine. Also, additives may be utilized which enhance taste and appearance, e.g., flavoring or coloring agents.

5 In a preferred embodiment, the tablets are coated such that they are selectively released in the stomach or intestine. With respect thereto, coatings which are acid-stable and allow for drug release in the intestine (referred to generally as enteric coatings) are well known. Examples include shellac and derivatives thereof, cellulose acetate phthalate, hydroxypropyl/methylcellulose phthalate, ethyl cellulose. Such enteric coating and methods for application thereof are discussed in detail in *Remington's Pharmaceutical Sciences*, (*Id.*) Also, U.S. Patents 4,017,647 and 4,287,221 are exemplary of enteric  
10 coated drug formulations. The enteric coated form should enhance the antimicrobial properties of the powder.

Alternatively, and preferably in the case of subjects that find solid dosage formulations difficult to take (which may be a significant concern in AIDS patients who at latter stages may have swallowing problems), the subject materials may be produced  
15 in the form of liquid elixirs, or other liquids. This can be effected by combining the subject *Allium* powder with fruit or other vegetable juices, sugars, flavoring materials, or other materials having known application in liquid drug formulations. This is further advantageous for subjects that find the taste of the subject material disagreeable. Still alternatively, the subject material may be combined with solid foods, e.g., in order to  
20 camouflage the taste, if desired.

As noted, a less preferred means of administration will comprise injectable formulations. In this embodiment, the powder will be combined with an injectable liquid, e.g., buffered saline, and injected by known routes, e.g., intravenous, intramuscular, intradermal, or subcutaneous routes of administration. For example, a subject with an  
 5 AIDS-associated lesion may be injected at the site of lesion to elicit an immune modulating or T-cell response.

Other modes of administration include topical, inhalatory, intranasal, sustained release implants, and rectal or vaginal suppositories.

The amount of particles which are administered, e.g., orally, injection, suppository,  
 10 intranasal, will typically range from about 5-50 grams per day, and more preferably about 9 to 13 grams per day. A particular advantage of the medicament of the present invention is that there are no known side effects. Consequently, there are no real upper dosage ranges.

A general description of properties of the subject material is summarized below.

15 1. **Description of the Medicinal Allium Product of the Invention**

Properties of the medicinal product of the invention were evaluated by placing 10 grams of this material in 500 ml of boiled water and heated for 10 minutes. The rehydrated vegetable exhibited the following characteristics:

	<b>Look &amp; Color</b>	<b>Flavor</b>	<b>Aroma</b>
20	White flakes with some green particles	Characteristic	Characteristic

2. Granulometric

Retained on sieve	USA 3/8 (9.5 mm)	5% max
Retained on sieve	USA 8 (2.36 mm)	90% min
Through sieve	USA 8	5% max

5

3. Humidity

Max 5.5%

4. Microbiological Analysis

Total Aerobic Mesophiles	300,000	ufc/g	Maximum
Total Coliforms	1,000	NMP/g	Maximum
E. coli	Negative		
Reduce sulphite Clostridium	10	ufc/g	Maximum
Yeast and Molds	1,000	ufc/g	Maximum

10

15

As noted above, the subject materials can be stored for prolonged periods prior to usage, preferably by storing in a dry, ambient temperature conditions, i.e., about 18-25°C, preferably in the dark to avoid oxidation. Preferably, the material will be stored in a sealed plastic bag or other container to maintain low humidity and avoid microbial or other contamination.

20

As discussed previously, the subject medicament has a number of different properties that render it well suited for use as a therapeutic. For example, it has been found that the subject *Allium* derived medicament has broad antiviral activity. The

subject extract may be used to treat or prevent a variety of different viral infections, both human and animal viruses. Examples thereof include retroviral infections such as AIDS, herpes (genital, rectal, oral), distemper, papillomavirus, flu associated influenza viruses, parvoviruses, rhabdoviruses, Epstein Barr virus, CMV, hepatitis virus, RSV,  
5 rhinoviruses, and foot and mouth disease virus.

In the preferred embodiment, the subject *Allium* derived medicament will be used for the treatment of AIDS. Entirely unexpectedly, it has been found that administration of the subject medicament to patients with AIDS results in disappearance of elimination of the clinical symptoms associated therewith, such as wasting syndrome, paresthesia  
10 intestinal colic, diarrhea, polyadenopathy, and HIV related infections. To date, these results have been observed in eight different patients having an age ranging from 28 to 38, many of which were in the latter terminal ("C-stage") of AIDS. These clinical results are summarized in the example *infra*.

In effecting the HIV treatment protocol of the invention, patients with AIDS will  
15 be withdrawn from anti-AIDS conventional medications such as protease inhibitors, anti-retrovirals, cytotoxic drugs, steroids, chemotherapies, and preferably will be placed on a restricted diet developed by the inventors. The use of tobacco and other smoking products or narcotics is also forbidden.

This diet preferably comprises ingestion of only natural products (without  
20 preservatives, and chemical additives) such as vegetables, fruits, fish, meat in small

quantities, no fried foods, no alcoholic beverages, no caffeinated beverages such as coffee, tea, and no sweetened drinks such as sodas. The use of tobacco and other smoking products, or narcotics, is also forbidden. If intestinal irregularities result because of ingestion of large amounts of vegetables and fruit, this preferably will be treated by  
5 ingestion of rice, white bread, cheese, apples or lemon. However, if necessary an anti-diarrheic medicine may be administered. Moreover, if significant weight loss results, then unfried potatoes, preferably about 250 grams twice a day may be ingested.

The subject AIDS therapy will comprise administration, preferably about 9-13 g/day of the subject medicament. Preferably, this will be effected orally, e.g., in capsule  
10 form by mixing in a suitable beverage or with food. However, other known modes of administration can be used. This treatment should be continued for the life of the patient. A maintenance dose is established once the patient is free of symptoms. This maintenance dosage typically will range from about 5-7 g/day. In fact, it has been observed for some patients who have stopped this treatment, that AIDS symptoms have  
15 relapsed. However, when these patients resumed the subject treatment, remission (absence of clinical symptoms) again resulted. Ideally, the treated patients will also undergo an exercise regimen/regime to help enhance overall wellness.

Also, the subject medicament may be used to treat other conditions. In particular, the subject medicament may be used to modulate the immune system, stimulate the  
20 immune system, and/or enhance T cell function and/or proliferation in subjects in need

of such treatment. Examples where such treatment will be of therapeutic benefit include boosting the immune systems of aged or immunosuppressed persons, persons with cancer, and persons with infection. In particular, the subject medicament has application in treatment and/or prevention of microbial infection, e.g., by fungi.

5           Still further, the subject medicament may be used to induce weight gain in persons in need of such treatment, e.g., those suffering from anorexia.

These treatments will be effected substantially the same as AIDS treatment, i.e., an effective amount of the subject *Allium cepa* material will be administered, preferably by oral administration, typically a daily dosage of about 9-13 g/day or more.

10           Also, the subject medicament may be used to treat infections, e.g., viral or bacterial infections, in animals such as dogs, cats, and birds. In fact, the means by which the subject medicament was initially shown to be effective involved treatment of a dog with parvovirus infection. As with AIDS treatment, this treatment has been observed to totally eradicate the clinical symptoms of the disease in the treated animal. Other animal  
15           diseases which have been treated include distemper, and *psittacosis*.

Still other diseases and conditions treatable with the subject *Allium* extract include candidiasis, e.g. pneumonia, caused by *Pneumocistis carinii*, urinary infection, and mycosis.

**EXAMPLE**

*Allium cepa* extracts produced according to the invention were orally administered to eight persons that are HIV<sup>+</sup>, most of them with full blown AIDS. In fact, some of these persons were close to death when treatment initiated. Treatment comprised stopping  
5 conventional treatment, starting of the dietary regimen according to the invention, and oral ingestion of about 9 to 13 g/day of the subject *Allium* extract daily. As can be seen from the results in the Table below, dramatic results were achieved, i.e., all of these eight persons had a total remission of clinical symptoms associated with AIDS and were able to resume a normal life style after treatment.

CLINICAL CHARACTERISTICS OF PATIENTS WITH HIV INFECTION TREATED WITH DIDANO-PLUS AND DIETARY REGIMEN											
PATIENT No.	103*	105	101	109	108	106*	107*	102*			
AGE	38	21	33	34	29	31	30	30			
SEX	M	M	M	M	M	M	M	M			
DATE HIV DIAGNOSIS	1991	1994	1994	1993	1993	1996	1994	1997			
TOXIC CATEGORY	C2	C2	C2	B.1	A.1	C.1	B.1	C.1			
STARTING DATE	9-1-97	6-16-97	6-24-97	6-4-97	10-6-93	3-25-96	1-28-94	11-10-97			
PREVIOUS MEDICATION	ANTIBIOTICS (BACTRIM)	ANTIBIOTICS, ANTACIDS	NO	NO	NO	NO	ANTIBIOTICS (BACTRIM)	SUSPENDED ANTIRETROVIRALS 8 DAYS AGO			
ADENOPATHY	INGUINAL BILATERAL LEFT ADMITT	NO	OCCIPITAL CERVICAL	POLYADENOPATHY	NO	ADENOPATHY, CERVICAL, ADMITT	CERVICAL-ADMITT BILATERAL	POLYADENOPATHY			
CONSTITUTIONAL SYNDROME	<WEIGHT, INTERSTITIAL DIARRHEA, 38°C PERSISTENT	39°C	<WEIGHT, 47 KG 90 DAYS, INTERMITT. UP TO 38°C	<WEIGHT FEVER	NO	<4 KG-4 MO. INTERMITT. DIARRHEA, FEVER	<4 KG. CONT. DIARRHEA, FEVER	<18 KG-4 MONTHS CONT. DIARRHEA, FEVER 38°C			
HISTORY OF HIV RELATED INFECTIONS	ORAL/RECTAL HERPES, OROFARYNGEAL MICROSIS, PNEUMONIA	ORAL HERPES, ORAL MICROSIS, PNEUMONIAS	ORAL HERPES, PNEUMONIA	NO	NO	PNEUMONIAS	PNEUMONIAS	RECTAL HERPES, SYPHILITIS, PNEUMONIAS, URINARY INFECTIONS			
Gastro-intestinal symptoms	EPIGASTRALGIA, ANOREXIA, DIARRHEA, INTERSTITIAL COLICUS	NAUSEA, ANOREXIA, INTERSTITIAL COLICUS	INTERMITT. DIARRHEA, INTERSTITIAL COLICUS	NO	NO	ANOREXIA	ANOREXIA	INTERSTITIAL COLICUS, PNEUMONIA, SURGERY ON 10-97			
OTHER CLINICAL ASPECTS	PARASTHESIAS OF LOWER LIMBS, DEPRESSION, RIGHT ORCHITIS	SEVERE SHORTNESS OF BREATH, OXYGEN THERAPY, RESERVED PROGNOSIS	DEPRESSION, GENERAL DISCOMFORT, ANXIETY	DEPRESSION, SUBMAXILLARY ABSCESS	NO	GASTRITIS, ANOREXIA	TREATED IN BUENOS AIRES FOR PNEUMONIAS	OPENED INFECTED SURGERY WOUND, EMACIATION, DYSPNEA III/IV, TERMINAL PATIENT			

CLINICAL CHARACTERISTICS OF PATIENTS WITH HIV INFECTION TREATED WITH DIDANUO-PLUS AND DIETARY REGIMEN									
PATIENT No.	103*	105	101	109	106	104*	107*	102*	
EVOLUTION JAN-FEB '98	GAINED 4 KG, NO INFECTIOUS SYMPTOMATOLOGY, GOOD GENERAL CONDITION	> WEIGHT, PHYSICAL EXAMINATION NORMAL	PHYSICAL EXAMINATION NORMAL	PHYSICAL EXAMINATION NORMAL	PHYSICAL EXAMINATION NORMAL	PHYSICAL EXAMINATION NORMAL	PHYSICAL EXAMINATION NORMAL	>10 KG TO DATE, PALENESS WEAKNESS GOOD PROGRESS	
EVOLUTION DECEMBER '99	ALL PATIENTS ARE CURRENTLY IN GOOD CONDITION, PHYSICAL EXAM NORMAL (**)								

PNEUMONIAS: 80% PNEUMONIAS WITH PNEUMOCYSTIS CARINII (PCP)  
20% PNEUMONIAS W/COMMON GERMS (COCOS)

\* RECEIVED ANTI-RETROVIRALS UNTIL STARTING WITH I+ (*Allium cepa* extract according to the invention)

\*\* PHYSICAL EXAMINATION NORMAL

- VITAL SIGNS WITHIN NORMAL LIMITS (BP, PULSE, TEMPERATURE IN DEGREES CELSIUS AND RESPIRATORY RATE)

- NO WEIGHT LOSS
- NO ADENOPATHIES
- NO DIARRHEA
- NO AIDS RELATED INFECTIONS

- RESPIRATORY, CARDIO-VASCULAR, ABDOMINAL, GENITO-URINARY, RECTAL AND NEUROLOGICAL EXAMS, ALL NORMAL